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UNITED STATES BANKRUPTCY COURT
DISTRICT OF NEW JERSEY

In re: ACETO CORPORATION, *et al.*,[1] Debtors.	Chapter 11 Case No. 19-13448 (VFP) (Jointly Administered)
KAVOD PHARMACEUTICALS LLC, f/k/a RISING PHARMACEUTICALS, LLC, f/k/a/ RISING PHARMACEUTICALS, INC.; and KAVACK PHARMACEUTICALS LLC, f/k/a PACK PHARMACEUTICALS, LLC, Plaintiffs, v. APEX PHARMACEUTICALS, INC., Defendant.	Adv. Pro. No.:

ADVERSARY COMPLAINT, OBJECTION TO CLAIM NOS. 147 AND 148 AND COUNTERCLAIM AGAINST APEX PHARMACEUTICALS, INC.

[1] The Debtors in these chapter 11 cases and the last four digits of each Debtor's taxpayer identification number are as follows: Aceto Corporation (0520); Tri Harbor Chemical Holdings LLC (f/k/a Aceto Agricultural Chemicals LLC, f/k/a Aceto Agricultural Chemicals Corporation) (3948); Tri Harbor Realty LLC (f/k/a Aceto Realty LLC) (7634); Kavod Pharmaceuticals LLC (f/k/a Rising Pharmaceuticals, LLC, f/k/a Rising Pharmaceuticals, Inc.) (7959); Kavod Health LLC (f/k/a Rising Health, LLC) (1562); Kavris Health LLC (f/k/a Acetris Health, LLC) (3236); KAVACK Pharmaceuticals LLC (f/k/a PACK Pharmaceuticals, LLC) (2525); Arsynco, Inc. (7392); and Acci Realty Corp. (4433).

Kavod Pharmaceuticals LLC, f/k/a Rising Pharmaceuticals, LLC, f/k/a Rising Pharmaceuticals, Inc. (collectively "Rising"); and KAVACK Pharmaceuticals, LLC, f/k/a PACK Pharmaceuticals, LLC ("PACK," and collectively with Rising, the "Plaintiffs"), by way of adversary complaint, hereby files this objection to proofs of claim numbers 147 and 148 filed by Apex Pharmaceuticals, Inc. ("Apex"), and counterclaims against Apex. Plaintiffs allege as follows:

NATURE OF ACTION

1. This is an adversary proceeding commenced pursuant to Federal Rule of Bankruptcy Procedures 7001, and sections 101 and 502 of the Bankruptcy Code. Plaintiffs seek the entry of an order (i) disallowing Claim Nos. 147 and 148 filed by Apex; (ii) awarding PACK damages against Apex in an amount to be determined by the Court due to Apex's breach of contract; (iii) pre-judgment interest at the maximum rate allowed by law; (iv) to the extent that either of Apex's claims are allowed in any amount, authorization for PACK and/or Rising to effectuate a setoff of any claim awarded to Apex against PACK and/or Rising's claims against Apex; (v) recovery of Plaintiffs' reasonable attorneys' fees, costs and other expenses incurred in connection with this adversary proceeding; and (vi) such other and further relief as may be just and proper under the circumstances.

JURISDICTION AND VENUE

2. On February 19, 2019 (the "Petition Date"), Aceto Corporation and certain affiliates, including the Plaintiffs (collectively, the "Debtors") filed voluntary petitions for relief under Chapter 11 of the Bankruptcy Code in the United States Bankruptcy Court for the District of New Jersey (the "Chapter 11 Cases").

3. The Debtors' Chapter 11 Cases are being jointly administered under Case No. 19-13448 (VFP).

4. No trustee or examiner has been appointed in the Chapter 11 Cases.

5. The Court has jurisdiction over this adversary proceeding pursuant to 28 U.S.C. §§157 and 1334(b) and the *Standing Order of Reference to the Bankruptcy Court Under Title 11* of the United States District Court for the District of New Jersey entered on July 23, 1984, and as amended on September 18, 2012.

6. This adversary proceeding is a core proceeding pursuant to 28 U.S.C. §157(b)(2)(A), (B), (C) and (O).

7. Pursuant to Bankruptcy Rule 7008, Plaintiffs' consent to the entry of final orders or judgments by this Court if it is determined that the Court, absent consent of the parties, cannot enter final orders or judgments consistent with Article III of the United States Constitution.

8. Venue is proper in this District pursuant to 28 U.S.C. §§1408 and 1409(a).

9. On or about June 11, 2019, Apex filed Proof of Claim No. 147 against PACK asserting an unsecured claim in the amount of $83,128,500.

10. On or about June 11, 2019, Apex filed a Proof of Claim No. 148 against Rising asserting an unsecured claim in the amount of $83,128,500.

PARTIES

11. The Plaintiffs are Debtors in these Chapter 11 Cases. PACK is a wholly-owned subsidiary of Rising. Both Debtors had a previous place of business located at Park 80 West, Plaza 1, 250 Pehle Avenue, Suite 601, Saddle Brook, New Jersey.

12. Upon information and believe, Apex is a privately held pharmaceutical company that claims to be in the business of the development and manufacturing of drug products. Upon

information and belief, Apex is a New Jersey corporation with a principal place of business located at 3005 Hadley Road, Suite 8, South Plainfield, New Jersey 07080.

FACTS COMMON TO ALL COUNTS

13. Effective as of April 2, 2010, PACK and Apex entered into a Product Development, Purchase & License Protocol Agreement (the "Product Development Agreement").

14. In the first recital to the Product Development Agreement, Apex asserted it was "engaged variously in the businesses of formulating, developing, and obtaining regulatory approval for generic pharmaceutical products."

15. Apex and PACK "agree[d] to cooperate, on a non-exclusive basis, to identify mutually agreed upon generic pharmaceutical products for eventual commercial introduction into the United States of America, its territories and commonwealths, including Puerto Rico (the "Territory")." Product Development Agreement at section 1.1.

16. Upon identifying such products, Apex and PACK agreed to "amend this Agreement by mutually executing and appending an Amending Exhibit that specifies the unique contractual terms applicable to such generic pharmaceutical product." *Id*.

17. Apex further agreed that under any Amending Exhibit, "Apex will formulate, develop, and technology transfer the generic pharmaceutical product" to the contract manufacturer. *Id*.

18. The Product Development Agreement specified that time was of the essence with respect to Apex's obligations to formulate and develop the products. *Id*. at section 1.2. Apex and PACK acknowledged that "for the program contemplated in this Agreement to succeed, the contemplated Products must be formulated and developed well in advance of the legally

permissible introduction into the market in order to arrange for and accomplish the necessary manufacture, regulatory submissions and approvals, sales, marketing and distribution all in time to capture sufficient market share to achieve profitability." *Id*.

19. The entire framework of the Product Development Agreement was conditioned upon Apex's ability to formulate and develop bioequivalent generic products once identified by Apex and PACK. The importance of "bioequivalence" in the generic pharmaceutical industry relates to the ability to obtain the U.S. Food and Drug Administration ("FDA") approval to place the drug on the market. If, as happened, Apex failed to deliver compliant products in a timely manner, it would thwart all further efforts to commercialize and monetize the product.

20. The initial term of the Product Development Agreement expired on March 31, 2015. *Id*. at section 8.1. A subsequent renewal period was available only for an additional two years through and including March 31, 2017. *Id.*

21. On or about April 8, 2010, Apex and PACK entered into Amending Exhibit #1 to the Product Development Agreement ("Amending Exhibit #1").

22. Pursuant to Amending Exhibit #1, Apex was "responsible for formulating and developing," among other products, Potassium Chloride Tablets and Meclizine HCI Tablets, "and the processes necessary for the manufacture of the Products." Amending Exhibit #1 at page 1. Apex's responsibilities included "all pre-formulation and prototype development," "all analytical method development," "formulation development," "performing stability studies," "compliance with all process and patents for Active Pharmaceutical Ingredients" and training of contract manufacturing staff. *Id*.

23. For each of the Products covered by Amending Exhibit #1, Apex agreed to meet specific development deadlines. These deadlines included:

Potassium Chloride Tablets

a. July 30, 2010: "Successfully complete analytical development." *Id*. at II.A.2.

b. August 30, 2010: "Successfully complete the formulation of a prototype and achieve the 3M Accelerate chemical stability." *Id*. at II.A.3.

c. October 30, 2010: "Perform scale-up assessment of the formulation and processes in preparation for technical transfer" to the contract manufacturer. *Id*. at II.A.4.

d. November 30, 2010: "Cause the successful passing of the Bio-Study…." *Id*. at II.A.5.

e. April 30, 2011: "Apex shall cause the Product to pass the pivotal Bio-Study." *Id*. at II.A.7.

Meclizine HCI Tablets

a. May 30, 2010: "Apex shall perform scale-up assessment of the formulation and processes in preparation for technical transfer" to the contract manufacturer. *Id*. at II.C.2.

24. Effective July 15, 2010, Apex, PACK, Custo pharm, Inc. ("Custopharm") and Thinq Pharmaceuticals-CRO PVT Limited ("Thinq") entered into a Four-Party Amending Exhibit (the "Four-Party Agreement").

25. Pursuant to the terms of the Four-Party Agreement, each of the parties thereto agreed to place responsibility for obtaining FDA approval of the Potassium Chloride Tablets on Custopharm. The Four-Party Agreement also placed responsibility for identifying and managing the contract manufacturer for Potassium Chloride Tablets on Thinq. Four-Party Agreement at articles 2 and 3.

26. On or about February 14, 2012, Apex and PACK entered into Amending Exhibit A to the Product Development Protocol Agreement for Chlorthalidone 15, 25 and 50 mg. (the "Amending Exhibit A").

27. Pursuant to Amending Exhibit A, Apex was "responsible for formulating and developing" the Chlorthalidone tablets "and the processes necessary for the manufacture of the

Product." *Id*. at page 1. These responsibilities included "all pre-formulation and prototype development," "all analytical method development," "formulation development," "compliance with all process and patents for Active Pharmaceutical Ingredients," and training of contract manufacturing staff. *Id*.

28. For each of the Products covered by Amending Exhibit A, Apex agreed to meet specific development deadlines. These included:

Chlorthalidone Tablets

a. September 15, 2012: complete development. *Id*. at II.D.2.a.

b. October 15, 2012: complete technology transfer to the contract manufacturer. *Id*. at II.D.2.b.

c. January 15, 2013: pass the bio-equivalence study. *Id*. II.D.2.c.

29. In addition, Amending Exhibit A contained project budgets for each phase. For example, Apex and PACK agreed to share the $120,000 cost to develop the product, the $60,000 cost to transfer the product technology, and the $200,000 cost to successfully complete the bio-equivalent study. *Id*. at II.D.2.

30. Apex breached the Product Development Agreement, Amending Exhibit #1 and Amending Exhibit A (collectively, "the "Agreements") by failing to formulate, develop and deliver products that PACK could commercialize and monetize within the specified time deadlines set forth and, as relevant, the budgets agreed to in the Agreements.

31. Apex failed to formulate, develop and deliver a bio-equivalent Potassium Chloride Tablet in breach of Amending Exhibit #1 with respect to Potassium Chloride Tablets and prevented the parties from pursuing the development of Potassium Chloride Tablets any further.

32. In breach of Amending Exhibit A, Apex also failed to formulate, develop and deliver a bio-equivalent Chlorthalidone tablet. Although PACK submitted the bio-equivalent

Chlorthalidone tablet for approval to the FDA, the FDA application was rejected because the product failed the Bio-study.

33. Similarly, the application made by Apex to the FDA for the Meclizine Tablets resulted in a lengthy deficiency letter being issued by the FDA. Because of delays in the process and the cost and time to address the deficiencies raised by the FDA, PACK was not able to secure a commercially reasonable return on investment were it to ultimately be able to obtain FDA approval and launch the Meclizine Tablets.

34. Following the FDA's refusal of the application for the Chlorthalidone tablets, PACK approached Apex with an offer to relinquish any prospective claim or interest relating to Apex's development of the Chlorthalidone tablets in return for reimbursement of PACK's investment. Apex rejected this proposal and filed a lawsuit against PACK and Rising in the Circuit Court of Cook County, Illinois, County Department, Law Division, No. 2017 L 003507 (the "Pre-Petition State Court Litigation"), on or about April 6, 2017.

35. Although Apex's inability to formulate, develop and deliver the Products, ultimately relieved PACK of any of its obligations under the Product Development Agreement, Amending Exhibit A, Amending Exhibit #1 and the Four-Party Agreement, PACK expended hundreds of thousands or millions of dollars in various efforts to advance the projects with Apex. PACK's significant investments could have and could have been avoided had Apex been forthright with PACK about Apex's inability to perform in accordance with the Agreements.

36. On April 30, 2014, Rising purchased 100% of the issued and outstanding membership interests in PACK.

37. At all times relevant to the term of the Agreements and through the Petition Date, PACK continued to and remained a separate entity.

38. At no point prior to the Petition Date was PACK merged into Rising.

39. At the relevant times to the Agreements, PACK maintained separate letterhead, purchase orders and invoices.

40. In the Pre-Petition State Court Litigation commenced by Apex, the complaint filed by Apex asserted a cause of action against both PACK and Rising for breach of contract (Count I), and a cause of action against both PACK and Rising for unjust enrichment (Count II). In Apex's complaint filed in the Pre-Petition State Court Litigation, Apex alleged it has "suffer[ed] damage in excess of $14 million, plus attorney fees and costs." PACK and Rising filed answers in the Pre-Petition State Court Litigation denying those claims.

41. PACK also filed a counterclaim against Apex in the Pre-Petition State Court Litigation asserting that Apex breached the Agreements. In addition, PACK and Rising asserted various affirmative defenses in the Pre-Petition State Court Litigation. Because of Apex's breach of the Agreements, Apex is not entitled to any damages or claim.

42. Inexplicably, in Apex's Proofs of Claim Nos. 147 and 148, Apex now asserts that PACK and Rising each owe it $83,128,500.

43. Apex's proofs of claim seek "Potential Product Loss Revenues" and a "Perpetual Loss" of revenue from the production of Chlorthalidone Tablets, Potassium Chloride Tablets and Meclizine HCI Tablets.

44. Plaintiffs object to Apex's proofs of claim for several reasons. First, as a result of Apex's breach of the Agreements, Apex is not entitled to damages, any future royalties or any other amounts.

45. Second, even if Apex were entitled to future royalties despites its breach of the Agreements, the Product Development Agreement determined that the amount of royalties, if

any, that would be due to Apex are equal "to a percentage of PACK's net profit as set forth in each Amending Exhibit," not the amounts sought by Apex. Product Development Agreement at section 3.1.

46. Third, Apex's proofs of claim seek damages for a period of time longer than is permitted under the Agreements between Apex and PACK. By way of example, for the Potassium Chloride Tablets, PACK's maximum obligation would be to pay Apex "a sum equal to 5% of the Net profit of the Product for three successive, full periods of one year in duration from the date of launch." Amending Exhibit #1 at II.A.10.

47. Fourth, even if Apex could maintain a claim despite its breach of the Agreements and establish a claim for amounts due, in the Product Development Agreement, Apex and PACK "expressly agree that the liability of the other Party for such breach shall be limited under this Agreement or otherwise at law or equity to compensatory damages only and in no event shall the other Party be liable for punitive or exemplary damages." Product Development Agreement at section 7.4.

48. Based on the foregoing limits contained in the Agreements, even if Apex could establish that it is entitled to damages despite its breach of the Agreements, the amount asserted due to Apex in its Proofs of Claim Nos. 147 and 148 are excessive and without foundation. The amounts asserted by Apex for Potassium Chloride Tablets, Meclizine Tablets and Chlorthalidone Tablets in its Proofs of Claim were not calculated in the manner required by the Agreements. Accordingly, Apex's Claim Nos. 147 and 148 are without merit and should be expunged.

COUNT I

(**Objection to Claim No. 147 Against PACK**)

49. Plaintiffs repeat and reallege the foregoing allegations as if set forth at length herein.

50. Pursuant to 11 U.S.C. section 502(b), PACK hereby objects to Apex Claim No. 147.

51. Apex's claims are barred, in whole or in part, because Apex materially breached the Agreements it had with PACK prior to any of the actions that Apex alleges constitute a breach by PACK.

52. Further, Apex failed to develop products within the allotted development time to be approved by the FDA as required by the Agreements and, therefore, prevented PACK from commercializing the Products.

53. Apex lacked the ability to serve as a contract manufacturer under the Product Development Agreement, Amending Exhibit A and Amending Exhibit #1.

54. Apex's claims are barred because section 7.4 of the Product Development Agreement provides that "[w]ith respect to a claim by one Party against the other Party arising out of the performance or failure of performance by the other Party under this Agreement, the Parties expressly agree that the liability of the other Party for such breach shall be limited under this Agreement or otherwise of law or equity to compensatory damages only and in no event shall the other Party be liable for punitive or exemplary damages."

55. Apex was obligated to mitigate its alleged damages with respect to its Proofs of Claim Nos. 147 and 148 for monetary relief. Apex's claims are barred because Apex failed to mitigate its damages.

56. In addition, as set forth below, PACK seeks damages against Apex because of its alleged breach of the Agreements. As such, PACK is entitled to an offset.

57. Further, Apex incurred certain of its alleged costs without any reasonable anticipation of reimbursement because Apex was either not entitled to reimbursement under the terms of the Agreements or because Apex was aware that PACK did not intend to pursue development of the products any further.

58. Apex has improperly calculated its alleged damages by failing to use the formula contained in the Agreements, and failed to present value of its alleged damages. Thus, Apex has inflated its alleged damages claim.

59. Apex also seeks damages for loss of revenue. To the extent that such damages are not barred by the limitation of liability provision of the Product Development Agreement, Apex failed to mitigate damages of this type because it did not make any other attempts to commercialize and/or market the Products, either itself or through others, that Apex alleges were ready to go to market.

COUNT II

(Objection to Claim No. 148)

60. Plaintiffs repeat and reallege the foregoing allegations as if set forth at length herein.

61. Pursuant to 11 U.S.C. section 502(b), Rising hereby objects to Apex Claim No. 148.

62. Rising is not a signatory to the Product Development Agreement, Amending Exhibit A, Amending Exhibit #1 or the Four-Party Agreement. Accordingly, Apex cannot seek to enforce any of these agreements against Rising.

63. On April 30, 2014, Rising purchased 100% of the issued and outstanding membership interests in PACK. Rising and PACK have remained separate entities through the Petition Date.

64. Rising is not PACK's successor in interest. As such, Rising can have no successor liability to PACK.

65. Without admitting that Rising is a party to any of the Agreements or has any successor liability hereunder, Rising states that to the extent that Apex is entitled to recovery on account of any of its claims against PACK and/or Rising, any such recovery is subject to a setoff against amounts owed by Apex to PACK for Apex's breach of the Agreements.

66. Rising hereby incorporates all of the other defenses to Apex's Claim No. 148 set forth in Count I above as if set forth at length herein.

COUNT III

(**Breach of Contract**)

67. Plaintiffs repeat and reallege the foregoing allegations as if set forth at length herein.

68. The Agreements were valid and enforceable contracts by and between Apex and PACK.

69. As set forth above, Apex breached the Product Development Agreement, Amending Exhibit A and/or Amending Exhibit #1.

70. Although PACK was ready and willing to perform its obligations under these Agreements, PACK's performance was hindered or rendered impossible by Apex's non-performance.

71. As a direct and proximate result of Apex's breach of the Product Development Agreement, Amending Exhibit A and/or Amending Exhibit #1, PACK incurred substantial losses, including damages, costs and expenses relating to PACK's efforts to advance the project under the Agreements. As a result, PACK has been damaged in an amount to be proven at trial, plus pre-judgement interest at the maximum rate allowed by law.

COUNT IV

(Setoff)

72. Plaintiffs repeat and reallege the foregoing allegations as if set forth at length herein.

73. To the extent that it is determined that there are any monies owed to Apex by PACK and/or Rising, PACK and/or Rising are entitled to setoff the amount asserted to be owed by Apex as a result of Apex's breach of the Product Development Agreement, Amending Exhibit A and/or Amending Exhibit #1.

74. Plaintiffs have valid setoff rights under applicable law, including but not limited to sections 553 and 558 of the Bankruptcy Code, and any claim by Apex should be offset by the amounts owed by Apex to the Plaintiffs.

COUNT V

(Attorneys' Fees, Expenses and Costs)

75. Plaintiffs repeat and reallege the foregoing allegations as if set forth at length herein.

76. Pursuant to section 9.8 of the Product Development Agreement, "[i]n the event any Party to this Agreement litigates or arbitrates the interpretation, construction or breach of

this Agreement, the prevailing Party in that action shall be entitled to a determination, award, and judgment in that same litigation of reasonable attorneys' fees and costs, and related expenses."

77. Accordingly, Plaintiffs are entitled to recovery their reasonable attorneys' fees, expenses and costs incurred in the prosecution of this adversary proceeding.

WHEREFORE, Plaintiffs request the Court enter judgment against Apex:

(i) disallowing Claim No. 147 in its entirety;

(ii) disallowing Claim No. 148 in its entirety;

(iii) determining that Apex breached the Product Development Agreement, Amending Exhibit A and/or Amending Exhibit #1 and, as a result, fix the amount of damages sustained to PACK as proven at trial, plus pre-judgement interest at the highest rate allowed by law;

(iv) to the extent that either of Apex's claims are allowed in any amount, authorization for PACK and/or Rising to effectuate a setoff of any claim awarded to Apex against PACK and/or Rising's claims against Apex;

(v) awarding Plaintiffs reasonable attorneys' fees, costs or other expenses incurred in the preparation and prosecution of this adversary proceeding; and

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(vi) granting Plaintiffs such other and further relief as the Court deems just and equitable.

Dated: July 30, 2019

Respectfully submitted,

LOWENSTEIN SANDLER LLP

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